#### **USARIEM TECHNICAL REPORT T08-01**

# DEMONSTRATION OF REAL-TIME PHYSIOLOGICAL STATUS MONITORING OF ENCAPSULATED 1<sup>ST</sup> CIVIL SUPPORT TEAM – WEAPONS OF MASS DESTRUCTION (CST-WMD) PERSONNEL

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#### **EXECUTIVE SUMMARY**

National Guard's Weapons of Mass Destruction Civil Support Teams (CST-WMD) have a requirement for a medical monitoring telemetry system to "assess status of downrange personnel" by observing "physiologic changes in vital signs and core temperature prior to collapse or loss of consciousness or death." The Warfighter Physiological Status Monitoring (WPSM) program has developed a wearable suite of sensors and algorithms to assess health state. In this study we demonstrated the WPSM – Initial Capability (WPSM-IC) system during a standard training exercise. We assessed the:

- Acceptability of a body-worn medical monitoring system to CST-WMD team members
- Ability to remotely provide physiological information to the command center
- Usefulness of the medical monitoring system to the CST-WMD medical officer in monitoring down-range team members' physiological state
- Acceptability of the graphical presentation of real-time physiological information to medical and/or command staff personnel.

Twelve male1st CST-WMD Massachusetts National Guard members plus their medical officer who observed and monitored the training event, but didn't wear the medical monitoring system participated in this study. The Vital Sign Detection System (VSDS) and medical hub components of the WPSM-IC system were worn during several two to three hour enclosed-space training exercises performed over two days. Each exercise had one or more simulated casualties in a small enclosed space. In the first exercise, access to the enclosed spaces was constrained to approximately 30" diameter access holes. During each exercise, remote monitoring of six team members took place with data transmitted to a base station laptop for display on a graphical user interface (GUI). Meteorological and micro-meteorological conditions surrounding and within the enclosed training spaces were measured. Real time physiological information was provided every 15s for all team members fitted with a medical monitoring system throughout the training events. There was minimal loss of data (mean loss =  $1.1 \pm$ 1.4%; 5% in the worst case). Most data were within physiologically reasonable bounds (98.7%). Heart rate and skin temperature data were similar to laboratory data collected using reference instrumentation. Respiration rate data was more variable and appeared to be less valid. The cause of this problem was detected to be a firmware error that has since been corrected. Information obtained from survey responses indicated the VSDS met the needs of CST-WMD missions, and could be used for real-time monitoring of CST-WMD personnel during missions lasting eight hours or less. Skin irritation could be an issue for some individuals, especially for longer duration missions (>8 hours). The simple GUI, which listed individual heath status information, was found to be adequate for CST-WMD medical monitoring purposes. The currently available WPSM system, when combined with commercial off-the-shelf radios, was shown to meet most of the CST-WMD medical monitoring telemetry requirements as detailed by the national CST-WMD medical working group.

#### INTRODUCTION

National Guard Weapons of Mass Destruction Civil Support Teams (CST-WMD) were founded with the mission of responding rapidly to domestic chemical, biological, radiological, and nuclear (CBRN) threats. Response to CBRN threats often means that team members will be encapsulated within some level of personal protective equipment (PPE) ranging from Level C, similar to Military Operational Protective Posture (MOPP) IV, to Level A which requires encapsulation within an impermeable suit with the use of self-contained breathing apparatus (SCBA) or a re-breather (1). When encapsulated in various levels of CBRN protection, the ability of the human body to thermoregulate is reduced (2). With high or even moderate work rates, heat production can exceed the body's capacity for heat loss leading to heat illness and possible collapse. Thermal strain has also been suggested as a possible contributing factor in the sudden cardiac death of firefighters -- the leading cause of US firefighter deaths (3) -- where the cardiovascular system is stressed from the competing needs of thermoregulation and strenuous work (4).

Recognizing the need to monitor thermal/work strain when encapsulated, the National CST-WMD medical working group generated a requirements document for a medical monitoring telemetry system (See Appendix A). The problem they cited is that it is "Difficult to assess status of downrange personnel verbally. Most casualties demonstrate physiological changes in vital signs and core temperature prior to collapse or loss of consciousness/death." The requirement calls for a system that monitors core body temperature, heart rate and cardiac rhythm (electrocardiogram (ECG)), respiration rate, pulse oximetry, and ambient temperature remotely; and successfully transmits this data back to a medical officer. Except for pulse oximetry, USARIEM's Warfighter Physiological Status Monitoring – Initial Capability (WPSM-IC) system monitors the physiological parameters of interest to the CST-WMD medical working group.

The WPSM-IC system (Figure 1) (5, 6) provides physiological and health state information to Soldiers, medics, and commanders. This system is comprised of a medical hub which hosts a personal area network of physiologic and medical sensors and a number of algorithms. The algorithms, using personal characteristics and sensor data, estimate the state of the Warfighter in the following areas: thermal, hydration, sleep history, and life signs. Health state information, along with summarized physiologic data, is intended to be a tool that medics and/or commanders can use to assess the health and readiness of their Warfighters.

The WPSM-IC system was tested at the US Army Aberdeen Test Center's (ATC) Military Operations in Urban Terrain (MOUT) test facility (Aberdeen Proving Ground, MD) in June 2006. Periodically over two days, health state and physiologic parameters were telemetered from 9 volunteers back to a base station via commercial radio modems. The results of this initial field demonstration of the WPSM-IC system (7) suggest it could also be used to meet the medical telemetry needs of the CST-WMD.

Figure 1. Warfighter Physiological Status Monitoring – Initial Capability system



Components: 1. Notional display on a PDA device; 2. Medical Hub that manages the network of sensors, communications, algorithms, and models (Hidalgo Ltd, Cambridge UK; Mini Mitter / Respironics Inc., Bend OR); 3. Vital Sign Detection System (VSDS) chest belt measures heart rate, respiration rate, skin temperature, body posture, and activity; this device has received FDA 510k pre-market approval as a heart rate, respiration rate and skin temperature monitor (Equivital; Hidalgo Ltd, Cambridge UK); 4. Core temperature telemetry pill (FDA 510k certified) (Mini Mitter / Respironics Inc., Bend OR), 5. Prototype fluid intake monitor measures fluid consumed.; 6. Sleep Watch measures apparent sleep history (Precision Control Design, Ft. Walton Beach FL).

The objective of the present study was to demonstrate the performance of the VSDS and medical hub part of the WPSM – Initial Capability (WPSM-IC) system which measures heart rate, respiration rate, skin temperature, and body motion and body position (VSDS) and stores and readies the information for transmission over a radio network (medical hub). The other components of the WPSM-IC system, e.g. the sleep watch, fluid intake monitor, etc. (Figure 1) were not used. Testing was done in an operationally-relevant CST-WMD training environment. We assessed the:

- The acceptability of the body-worn system to CST-WMD team members
- The ability to remotely provide physiological information to the command center
- The usefulness of this monitoring system to the CST-WMD medical officer in monitoring down-range team members

• The acceptability of the graphical presentation of the real-time physiological information to the medical and/or command staff personnel.

Additionally, meteorological and micro-meteorological conditions surrounding and within the enclosed space training spaces were measured to provide the environmental context this test took place in.

#### **METHODS**

The functionality of this medical monitoring system was assessed during a regularly scheduled CST-WMD training event. During this training event, CST-WMD team members wore the WPSM-IC system VSDS and medical hub. Data were transmitted in real time to a base station computer. The base station computer had a graphical user interface (GUI) that presented real time data from all instrumented team members.

#### **VOLUNTEERS**

Twelve male team members from the Massachusetts National Guard 1<sup>st</sup> CST-WMD served as volunteers (age =  $33.5 \pm 6.9$  yrs, height =  $181.4 \pm 6.1$  cm, body weight =  $89.9 \pm 8.4$  kg, two-mile run time =  $15.75 \pm 1.30$  min). One additional volunteer was the medical officer who observed and monitored the training event but did not wear a monitoring system.

#### TRAINING EVENT DESCRIPTION

Monitoring systems were worn during portions of two days of enclosed space training. Each training scenario had one or more simulated casualties in a small enclosed space. Access to the enclosed space was through holes that were approximately 30" in diameter.

#### **Day 1: Concrete Tank Training Exercise**

This enclosed space consisted of two large septic tanks (Figure 2). The septic tanks were stacked vertically with a single casualty (simulated) in the bottom tank. Access to the casualty was through the two access holes in each tank. The upper tank was floorless – resting on top of a second tank allowing entry through the access hole (Figure 2, Panel B).

The training scenario was run twice, with six of the twelve volunteers participating in the morning and the remaining six in the afternoon. In each training session one volunteer served as a casualty with the remaining five serving as the rescue team. The training scenario did not have a CBRN component to it; therefore volunteers wore Battle Dress Uniform (BDU) pants and t-shirts. The goal of the exercise was to locate and extract the unconscious (simulated) casualty. Extraction of the casualty was achieved

through a rope lift mounted to a tripod above the top septic tank access hole (Figure 2, Panel A). This hole also served as the access and egress point for the rescue team.

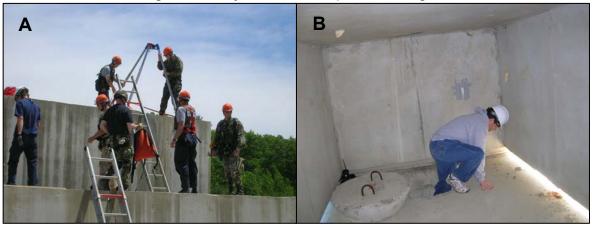


Figure 2. Day 1 enclosed space training site

Panel A shows the two concrete septic tanks used for the enclosed space training. Panel B shows the entrance to the lower septic tank.

# **Day 2: Fire Training Site Exercise**

The enclosed space for the second day of training consisted of two metal shipping containers converted into a fire training facility (Figure 3). Container windows and doors were shut during the exercise. Entrance to the structure was through an access hole located on the roof the containers.



Figure 3. Day 2 enclosed space training site

The goal of second day of training was to locate and extract a number of unconscious casualties who had succumbed to a chemical agent (conditions were simulated, i.e., no one was unconscious and no chemical agents were used). Since a chemical agent was suspected in the training scenario, rescuers wore Level C personal protective equipment (PPE) with an external air supply (Figure 4). Rescuers climbed to the top of the containers via a ladder. Casualties were extracted by physically carrying

or dragging the casualties to the bottom of the access hole and then utilizing a rope lift to move the casualties through the access hole to the container roof top. Six of the twelve volunteers participated in the second day of training. Three volunteers served as casualties and the remaining three served as rescuers.



Figure 4. Day 2 personal protective equipment

#### **EQUIPMENT**

# Physiological Monitoring

Each CST-WMD volunteer, except for the medical officer wore a physiological monitoring system consisting of the Vital Sign Detection System (VSDS) (<a href="http://www.hidalgo.co.uk/toplevel.htm?whatwedo-equivital.htm">http://www.hidalgo.co.uk/toplevel.htm?whatwedo-equivital.htm</a>) (Hidalgo Ltd., Swavesey Cambridge, UK), hub components of the WPSM-IC system, and a commercial-off-the-shelf (COTS) radio with battery pack (Table 1).

The VSDS consists of a textile chest belt that supports a hard plastic sensor electronics module (SEM) that snaps into the center of the belt. The VSDS derives heart rate from the electrocardiogram (ECG), respiration rate from chest wall contraction and expansion, chest skin temperature by thermister; chest orientation (upright, supine face down, etc.) and physical activity patterns are derived from a three-dimensional accelerometer housed in the SEM. The VSDS has received Food and Drug Administration (FDA) 510K pre-market certification as a heart rate, respiration rate, and skin temperature monitor, and also provides an index of medical status (6) based upon the presence or absence of motion, heart rate, and respiration.

Table 1. Physiological monitoring equipment used in the study

Device	Manufacturer	Data type	Wt. (g)
Vital Sign Detection System (VSDS)	Equivital; Hidalgo Ltd., Swavesey Cambridge, UK	Heart Rate Respiration Rate Skin Temperature Body Position Activity/inactivity Vital Sign State	193
WPSM Hub	Hidalgo Ltd., Swavesey Cambridge, UK	health state information (heart rate, respiration rate, temperature, activity/ inactivity) and system status (e.g., any error messages, battery charge)	340
Off-Body Radio	Digi XTend RF Modem; Maxstream Inc., Lindon, Utah	Telemeters Hub data to base station PC	208
Radio Battery	External Battery Pack (PM85-44)	N/A	321

Total weight worn is  $\sim$  1 kg). The COTS radio modems operate at 900 MHz using spread spectrum frequency hopping technology, and transmitted data every fifteen seconds from the Hub to a base station laptop computer. The radios were configured to allow simultaneous transmission of physiological data from six systems.

In this study the hub received data from the VSDS via Bluetooth<sup>tm</sup> radio frequency (RF) protocol, stored this information locally on a flash memory card, and exported the data to a long haul radio modem that transmitted the physiological data off-body to a command center.

Figure 5 shows the GUI used to present individual vital sign status, volunteer number, heart rate and trend, respiration rate and trend, chest skin temperature and trend, body/chest orientation, and time of last data update. These data, derived from each individual's physiological monitoring system outputs, were displayed in real-time for observation by study participants.

**▲ CST Medical Telemetry Monitor** Detail Diagnostics 1st CST - WMD **Medical Telemetry Monitor** Br/min Orientation Temp. 3060005 131 → 27  $\rightarrow$ 35.3 → 11:24:32 2 3060001 127 39 → 30.4  $\rightarrow$ 11:24:22  $\mathbf{\Lambda}$ Ť 11:24:29 3 1150001 121  $\rightarrow$ 32 36.1 → 3060004 90  $\rightarrow$ 36  $\uparrow$ 31.59  $\rightarrow$ 11:24:32 5 3060008 Ψ 30.09 Ť 11:24:19 96 → 28 → 1 3060012 25 34.7 11:24:25 134 →  $\rightarrow$ OK | Current Time: 11:24:35 🌖 C 🌑 R 🌑

Figure 5. Graphical user interface display

# **Environmental Monitoring**

Two types of meteorological monitoring systems were used. The Campbell Scientific Inc. (Logan, UT) CR-10X weather station (Figure 6, Panel A) was used to record ambient weather conditions and was configured to measure wind speed, wind direction, humidity, air temperature, solar radiation, and ground surface temperature. Weather data were logged to onboard memory for later download. On the first day of training, weather data were also transmitted via a 100 mW 900 MHz spread spectrum radio (Digi XTend RS-232/RS-485 RF Modem, Maxstream Inc., Lindon, Utah) to a laptop computer for display and redundant logging. In addition, up to 16 HOBO® Pro v2 temperature/RH loggers (Onset Computer Corporation, Pocasset, MA) (Figure 6, Panel B) were used to record temperature and relative humidity in the enclosed spaces.

Figure 6. Environmental monitoring equipment

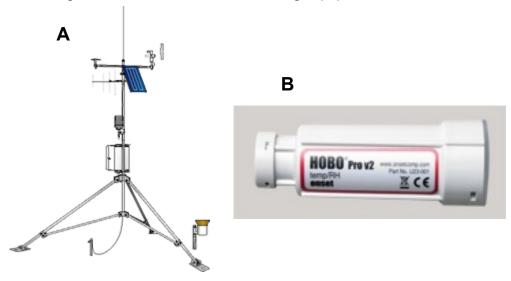


Figure 6A shows the Campbell Scientific Inc. (Logan, UT) CR-10X weather station. Figure 6B shows the HOBO® Pro v2 temperature/relative humidity (RH) logger (Onset Computer Corporation; Pocasset MA) which can log temperatures from -40 to  $70^{\circ}$  C  $\pm$  0.18° C and RH between 0-100%  $\pm$  2.5%.

#### **MEASURES**

# **Heart and Respiration Rate Signal Quality**

The medical monitoring system data was assessed by examining the availability and quality of its physiological information from six different systems as volunteers were them during training. Quality of the heart rate and respiration rate data was assessed by examining how many reported values were within a physiologically reasonable range and had reasonable variance for the given activity. The physiologically reasonable ranges and variance used were derived from VSDS laboratory validation study data (8).

The physiologically acceptable range was calculated for both heart and respiration rates in the following way. The minimum reasonable heart rate or respiratory rate was calculated as the minimum observed during sedentary sitting conditions minus two standard deviations (SD). Similarly, the maximum reasonable values were calculated as the maximum values observed during treadmill running (6 mph) plus two SDs. Rounded values, to the nearest integer, of the minimum and maximum rates were used. Table 2 shows VSDS study data (8) for heart and respiration rate values for volunteers at rest (sitting) and during physical activity (running), and the corresponding range (minimum/maximum) used in the current data analysis. Table 3 shows the calculated bounds using the two-SD method described above. That is, when heart rates were below 120 BPM, the acceptable data variability was calculated as two-times the SD deviation in heart rate and respiratory rate measured during sitting. Similarly, when heart rates were above 120 BPM, the acceptable variability was set at 2 times the SD for heart rate and respiratory rate measured during running.

Table 2. Heart rate and respiration rates (overall group mean and SD, N = 8) and calculated acceptable ranges (minima and maxima) for heart rates and respiration rates

(defined as laboratory values ±2SD)

	Sitt	Sitting		ning	Range		
	Value	SD	Value	SD	Min	Max	
Heart Rate <sup>1</sup>	74	6.6	153	15.7	61	184	
Respiration Rate <sup>1</sup>	16	2.1	38	6.1	12	50	

<sup>&</sup>lt;sup>1</sup> Group mean and SD calculated by pooling data from all subjects for a given condition (sitting or running).

Table 3. Parameter variance thresholds based upon lab validation study activities for periods where heart rate is above or below 120 BPM

periode interestical trace is described as selectives.								
	Acceptable	Acceptable						
	Heart Rate	Respiration Rate						
	variability	variability						
	(2 × SD)	(2 × SD)						
HR < 120 BPM	26	8						
HR ≥ 120 BPM	62	24						

# **Skin Temperature Data Quality**

Skin temperatures with a rate of change ≥ 1 °C / min were defined as outliers, and noted. Skin temperature in the VSDS is measured by an insulated thermistor embedded in a cloth electrode that forms part of the VSDS chest strap. Consequently, the signal variance over time tends to be minimal. Rather than increased data variability, aberrant data tend to be extraneous, outlier data points.

#### **VSDS Vital Sign Algorithm Performance**

The VSDS incorporates a vital sign detection algorithm. This algorithm is designed to determine the absence of or grossly abnormal heart activity, respiration, or movement. The algorithm provides five outputs: green – "OK", yellow – "look", red – "look now", gray – "absence of vital signs > 5 minutes, and blue – "unknown or fault" (6). In the present study, we anticipated only green or blue outputs since yellow, red, or gray outputs are usually associated with serious medical events. In this study, the analysis of VSDS algorithm output was limited to quantifying the number of false positives – that is; the number of times a state other than blue or green was output. The ratio of blue states to green states was also calculated.

## System Acceptability

A questionnaire was used to assess the acceptability of the VSDS to the CST-WMD team members (Appendix B). Subjective ratings of the VSDS components were collected for fit, comfort, performance effects, physical impact, and overall acceptability. A variant of this survey was recently used to assess the form, fit, comfort, and

performance acceptability while performing a training exercise in an urban combat environment (5).

User comments regarding the utility and manner of presentation of real-time physiological information were also obtained using a questionnaire (Appendix C). The GUI used during this experiment was designed following recommendations from U.S. Army medics (9), with the exception that personal identifiers were not used.

#### **PROCEDURES**

Before the start of each day's training exercise, meteorological and micrometeorological monitors were positioned near the training sites and set to log data. Physiological monitoring systems, except the VSDS, were pre-mounted to CST-WMD utility vests. When the volunteers arrived, they were fitted with a VSDS belt based upon chest size and the manufacturer's sizing chart. If a belt was too tight, an elastic extender was used to obtain the correct belt tension. A sensor electronics module (SEM) was turned on and snapped onto each volunteer's VSDS chest belt. The VSDS was deemed to be functioning when the device provided a pager-style triple buzz, and VSDS data reception at the base station laptop was confirmed. If no data was received at the base station, the VSDS and hub were reset.

Midway through the first day of training, when systems were exchanged between the first and second set of six volunteers, the VSDS belts were rinsed with water and left to dry for approximately one hour. At the end of each day, systems were retrieved from the volunteers. The VSDS belts were rinsed with water and left to air dry, and stored data were downloaded for subsequent analysis.

All volunteers were asked to view the base station GUI during their training exercise. After the training exercise, volunteers completed two surveys, one on GUI acceptability and one on the acceptability of the VSDS system itself.

#### STATISTICAL ANALYSIS

To examine whether average physiological parameters changed by training session, a single factor (training session) analysis of variance (ANOVA) was employed with level of significance set at p < 0.05. A Pearson's product-moment correlation coefficient was used to examine the level of association between selected variables. A two-tailed Student's independent samples t-test was used to examine differences between means from two groups where the level of significance was set at p < 0.05. Data are reported as mean  $\pm$  SD.

#### **RESULTS**

#### **METEOROLOGICAL CONDITIONS**

Figure 7 shows the air temperature, relative humidity, solar radiation, and wind speed for the two training exercises as measured by the Campbell Scientific CR-10X weather station. Day 2 was warmer and more humid than Day 1.

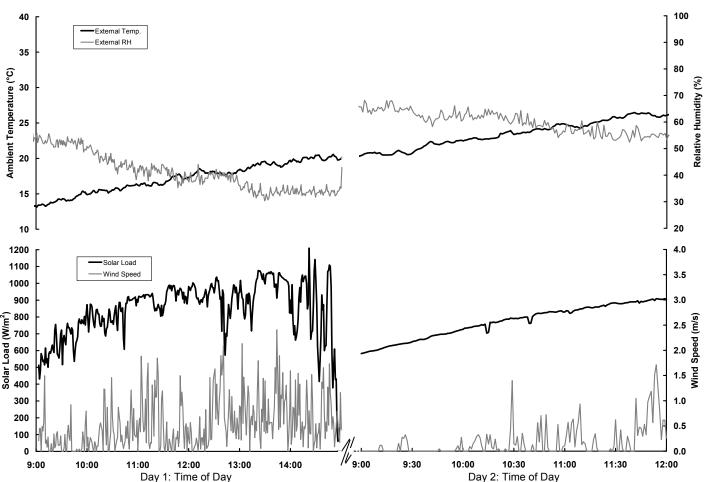


Figure 7. Local meteorological conditions for training days 1 and 2

The enclosed space temperatures from the HOBO® Pro v2 monitors are presented for Day 1 in Figure 8 and for Day 2 in Figure 9. Compared to the metal containers used during Day 2 training, the micro-meteorological conditions in the concrete tanks on Day 1 were more stable, with temperatures from all sensors generally within 1.5 °C of each other. For the same tank location (north, south, or east) the upper concrete tank was warmer than the lower. Conversely relative humidity was higher in the lower tank compared to the upper. Temperatures within the concrete tanks were similar to external air temperature.

At the firefighter training site (metal containers), the temperatures near the east facing container walls were warmer than those near the interior walls or north or west-facing walls by as much as 10 °C. Relative humidity in the metal containers shows a reverse trend, lowest on east, higher on the other walls and interior wall - a trend related to the "relative" function as the same amount of moisture in warmer air is "drier". Temperatures in the metal containers were between 5 °C and 12 °C warmer than the external temperatures, at the hottest points reaching as high as 38.5 °C (101.3 °F).

Figure 8. Day 1: Reinforced concrete enclosed space air temperature and relative humidity

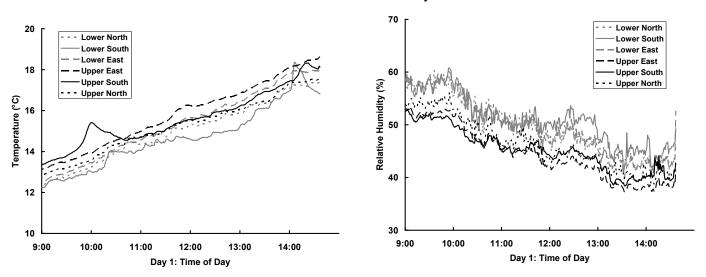
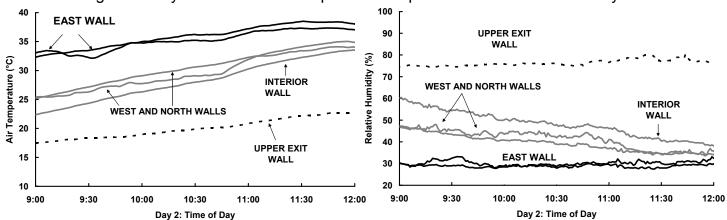


Figure 9. Day 2: Metal enclosed space air temperature and relative humidity



#### PHYSIOLOGICAL MONITORING

Data availability, and heart rate and respiration rate data quality are presented in Table 4 for each volunteer for each training session. Skin temperature data quality and vital sign detection algorithm performance are presented in Table 5. Overall, the VSDS performed similarly across the three training sessions for all volunteers, with 98.9% of

expected data received at the base station. Plots of data for each system can be found in Appendix D. An example of the time series physiological data is presented in Figure 10.

Table 4. Heart and respiration rate data availability and data quality for each test period

Table 4. Heart and respiration rate data availability and data quality for each test period													
	Heart Rate							Respiration Rate					
	Data	Out of				Large	Mean	Out of		١.,	l	Large	Mean
Subj	Rec'd (%)	Range (%) <sup>1</sup>	Min (BPM)	Mean (BPM)	Max (BPM)	Var. (%) <sup>2</sup>	SD (BPM) <sup>3</sup>	Range (%) <sup>1</sup>	Min (Br/M)	Mean (Br/M)	Max (Br/M)	Var. (%) <sup>2</sup>	SD (Br/M) <sup>3</sup>
		· /	/	. ,		(70)	(BEIVI)	(70)	(DI/IVI)	(DI/IVI)	(DI/IVI)	(70)	(DI/IVI)
		ng: Chas				40.0	0	0.0	4.5	0.7	0.0	00.0	0
1	99.5	0.0	62	89	135	12.3	8	0.0	15	27	38	22.6	3
2	98.8	0.0	68	82	105	0.0	5	1.4	15	30	60	48.1	5
3	99.0	0.0	85	105	137	10.0	8	0.0	16	26	38	17.1	3
4	100.0	0.0	70	86	118	5.3	7	0.0	13	23	36	24.9	3
5	100.0	3.8	9	99	119	6.0	5	1.5	11	23	35	18.3	3
6	100.0	0.0	71	94	149	17.5	8	0.0	15	29	48	60.0	5
Mean	99.6	0.6	61	92	127	8.5	7	0.5	14	26	43	31.8	4
Day 1	<ul><li>Afterr</li></ul>	oon: Cha	se Preca	st (1330 -	- 1420 h)	)							
7	100.0	0.0	72	92	141	8.5	8	0.0	16	27	42	48.5	4
8	100.0	0.0	72	86	117	7.5	6	0.0	15	26	40	35.5	4
9	100.0	0.0	83	99	129	2.5	6	0.0	19	29	42	46.0	4
10	100.0	1.0	42	100	127	8.5	7	0.5	7	25	34	17.5	3
11	100.0	0.0	91	120	146	6.3	10	0.6	8	28	37	21.1	4
12	97.0	0.0	64	89	126	14.5	9	3.5	11	28	57	76.0	6
Mean	99.5	0.2	71	98	131	8.0	8	0.8	12	27	42	40.8	4
Day 2	: Firefial	nter Train	ina Site (	0930 – 1 <sup>2</sup>	150 h)								
1	98.5	0.0	66	104	181	9.6	9	0.0	12	26	41	24.5	4
2	95.0	0.0	73	91	134	7.7	7	6.1	17	38	60	51.2	5
3	99.8	0.0	87	109	159	0.9	7	0.5	14	26	57	28.0	4
4	98.1	0.0	72	94	160	2.4	5	0.2	17	28	55	41.1	4
5	97.1	0.0	88	99	122	0.0	3	3.6	17	35	56	67.2	5
6	97.9	0.0	73	100	166	5.7	8	1.2	9	28	59	41.8	5
Mean	97.7	0.0	77	99	154	4.4	6	1.9	14	30	55	42.3	4
	d Mean							·					·
Mean	98.9	0.3	69	96	136	7.0	7	1.1	14	28	46	38.3	4

Out of Range: heart rate or respiration rate was outside the range defined in Table 2

<sup>&</sup>lt;sup>2</sup> Large Var.: large variability, that is, heart rate or respiration rate standard deviation exceeded pre-set standards.

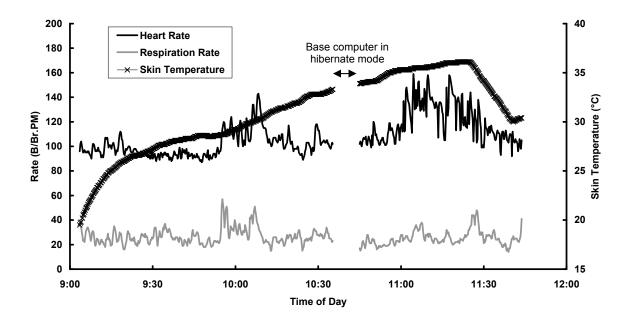
Mean SD: mean of the standard deviations of 4 minute moving average.

Table 5. Chest skin temperature data quality and vital sign algorithm state for each test period

				State it			2			
	Chest Temperature					Vital Sign Algorithm <sup>3</sup>				Ī
					High Rate of					
	Min	Mean	Max	Mean	Change	Blue	Green	Yellow	Red	Gray
Sub	(°C)	(°C)	(°C)	dT/dt <sup>1</sup>	(%) <sup>2</sup>	(%)	(%)	(%)	(%)	(%)
Day 1	<ul><li>Morni</li></ul>	ng: Cha	se Preca	ast (1015 –	· 1200 h)					
1	26.2	27.8	29.8	0.10	0.0	10.5	89.5	0	0	0
2	28.4	29.7	36.8	0.15	1.2	10.6	89.4	0	0	0
3	25.1	27.3	31.1	0.12	0.5	12.5	87.5	0	0	0
4	31.4	33.1	35.3	0.10	0.5	2.4	97.6	0	0	0
5	28.2	32.0	35.9	0.28	4.3	48.0	52.0	0	0	0
6	27.5	29.3	32.9	0.29	3.4	0.0	100.0	0	0	0
mean	27.8	29.9	33.6	0.17	1.6	14.0	86.0	0	0	0
Day 1	<ul><li>Aftern</li></ul>	oon: Ch	ase Pre	cast (1330	- 1420 h)					
7	27.8	29.8	31.1	0.19	0.0	19.7	80.3	0	0	0
8	26.8	28.5	29.8	0.18	0.0	6.5	93.5	0	0	0
9	26.3	27.3	29.0	0.34	4.5	7.0	93.0	0	0	0
10	27.9	29.1	30.2	0.15	0.0	12.4	87.6	0	0	0
11	30.3	31.5	32.3	0.12	0.0	14.2	85.8	0	0	0
12	29.8	31.8	33.4	0.18	2.6	14.4	85.6	0	0	0
mean	28.2	29.7	31.0	0.19	1.2	12.4	87.6	0	0	0
Day 2:	: Firefigh	nter Traii	ning Site	(0930 - 1)	150 h)					
1	23.3	30.6	35.7	0.12	0.0	7.2	92.8	0	0	0
2	27.3	30.5	33.2	0.12	0.7	62.3	37.7	0	0	0
3	25.0	31.4	36.1	0.13	0.0	4.3	95.7	0	0	0
4	31.0	31.9	33.3	0.16	3.9	0.7	99.3	0	0	0
5	29.9	31.5	33.0	0.09	0.4	22.1	77.9	0	0	0
6	30.4	32.9	36.2	0.11	0.4	11.2	88.8	0	0	0
mean	27.8	31.4	34.6	0.12	0.9	18.0	82.0	0	0	0
Grand	Mean									
mean	27.9	30.3	33.1	0.16	1.2	14.8	85.2	0	0	0

<sup>1</sup> Mean absolute rate of change of chest temperature (°C/Min)
2 Percentage of data points where the rate of change exceeds 1.0 °C/Min
3 Vital Sign Algorithm: Blue = "Unknown or Fault", Green = "OK", Yellow = "Look", Red ="Look Now", and Gray = "Absence of vital signs for > 5 min"

Figure 10. Representative time series heart rate, respiration rate and skin temperature data for one volunteer during Day 2 training



# **Heart Rate**

Over the three training sessions, average HR did not vary significantly (F = 0.98, df = 2, p = 0.40). The number of HR data points outside of the physiologically reasonable range was 0.3 ± 0.9%, and 0% for all but two volunteers. The percentage of data points where the surrounding data exhibited a large variance was also relatively modest (mean = 7.0 ± 4.8%).

## **Respiration Rate**

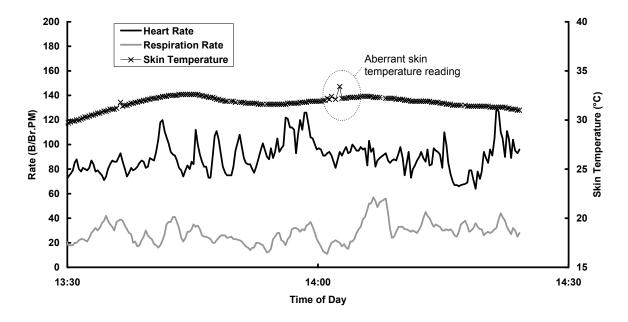
Over the three training sessions, average respiration rate did not vary significantly (F = 1.98, df = 2, p = 0.17). The number of respiration rate data points outside the physiologically reasonable range was modest  $(1.1 \pm 1.7\%)$ . However, the percentage of data points exhibiting a large variance was  $38.3 \pm 18.0\%$ , with substantial differences between volunteers. For example 76% of the respiration rate data exceeded the acceptable, pre-established acceptable level of variability (Figure 11). For the first two training sessions, where standing was predominant, the average respiration rate  $(26.8 \pm 2.3 \text{ Br/Min})$  was significantly (t = 9.97, df = 18, P < 0.01) higher than in the standing condition for the VSDS laboratory validation study  $(16.0 \pm 2.1 \text{ Br/Min})$ .

#### **Skin Temperature**

Average chest skin temperatures did not vary significantly over the three training sessions (F = 1.88, df = 2, p = 0.19). Chest skin temperature data changed gradually

(Figure 10), at an average rate of 0.16 °C per minute. Fewer than 2% of the skin temperature data points would be higher or lower than expected (Figure 11).

Figure 11. Data from a single volunteer from Day 1 training showing an example of an aberrant chest skin temperature reading, and excessively variable respiration rate data



#### **Vital Sign Detection Algorithm**

Table 5 shows the VSDS algorithm outputs listing the percentage of time each state was given for each volunteer for each event. No false positives were output by the algorithm. The average percent of time a "blue" state was given varied across volunteers (15  $\pm$  16%, median = 11%), with two volunteers receiving 48% and 62% blue state outputs. There was no correlation between the high respiration rate variance and the percentage of time a blue state was indicated (r = 0.06).

# SYSTEM ACCEPTABILITY

Volunteers (n = 12) wore the VSDS for 4.0 ± 2.6 hours (range: 1 to 8 h). When they were asked if the system fit properly, 11 of 12 volunteers said it did. The one volunteer who found the system did not fit properly said that he needed a VSDS chest strap extender to achieve a correct fit. Ratings for fit by body area are summarized in Table 6. Table 7 tabulates whether the device was too tight or too loose by body area.

Table 6. Fit of the Vital Sign Detection System (VSDS) for various areas of the body

	Dislike	Dislike	Dislike	Neither	Like	Like	Like Very
	Very Much	Moderately	Slightly	Like nor	Slightly	Moderately	Much
				Dislike			
Chest	0	0	1	1	2	5	3
Shoulders	0	0	0	2	0	7	3
Neck	1	0	0	1	0	7	3
Back	0	0	2	1	1	5	3
Overall	0	0	0	2	0	7	3

Table 7. Tightness/looseness of the Vital Sign Detection System (VSDS) for various areas of the body

	Very Tight	Moderately	Slightly	Neither	Slightly	Moderately	Very
		Tight	Tight	Tight nor	Loose	Loose	Loose
				Loose			
Chest	0	4	3	4	1	0	0
Shoulders	0	2	1	8	1	0	0
Neck	0	2	1	8	1	0	0
Back	0	1	4	6	1	0	0
Overall	0	1	4	5	1	0	1

With the exception of one individual, CST-WMD volunteers felt the VSDS was comfortable to wear. Figure 12 summarizes overall comfort ratings; while Table 8 summarizes comfort by the individual components of the VSDS (see VSDS component illustration in Appendix B, p. 35). With the exception of the chest strap adjustment fastener, the components were rated in the comfortable range. When volunteers who found the device uncomfortable in some way were asked if there was a specific activity when they experienced the discomfort, the three comments all dealt with the bulkiness of the device and its use in confined spaces. Comments offered were:

- "It pulled or compressed the chest."
- "With tight spaces it rubs against my chest."
- "With SCBA [self contained breathing apparatus], helmet, and gloves, we crawled through 30 inch or smaller tubes simulating confined space. The VSDS constricted movement. Pressured chest vest [i.e. we assume this means the hub and radio mounted on the volunteer's webbing gear – author added comment] was more of a problem than VSDS though."

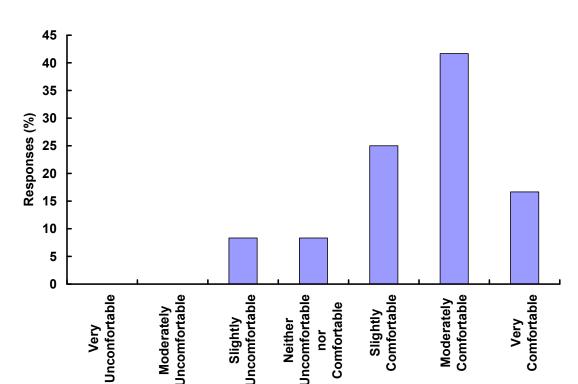


Figure 12. Vital Sign Detection System (VSDS) overall comfort rating

Table 8. Comfort of various parts of the Vital Sign Detection System (VSDS)

	Very Un- comfortable	Moderately Un- comfortable	Slightly Un- comfortable	Neither Un- Comfortable nor Comfortable	Slightly Comfortable	Moderately Comfortable	Very Comfortable
Electrodes	0	0	1	1	2	6	2
Water Proof Material	0	0	0	3	1	6	2
Central Belt Area	0	0	1	1	2	6	2
Belt Elastic	0	0	1	1	2	6	2
Belt Elastic Stitching	0	0	2	1	3	4	2
Shoulder Belt Adjuster	0	0	1	1	3	5	2
Adjustment Fastener	0	0	4	1	1	4	2

CST-WMD personnel were asked "Overall, from wearing the VSDS was there any negative impact on job performance? In response, 67% (8 of 12 volunteers) said there was no impact and the others (33%; 4 of 12 volunteers) said there was a slight negative impact on job performance. When specifically asked about how job performance was impacted in terms of ease of motion, ease of movement, and bending, 6, 5 and 4 individuals, respectively, stated that there was a slight negative impact on these activities from wearing the VSDS.

Two individuals cited that irritation of the skin on the back was a problem, with one individual specifically attributing the skin irritation to the adjustment fitting on the shoulder strap. Figure 13 is a photo of a test volunteer after wearing the VSDS showing

skin irritation on his back from the shoulder strap adjustment fitting. When asked if any of the VSDS components had any negative impact, two individuals cited the shoulder strap adjustment fitting. Table 9 lists the VSDS sub-components and the level of negative impact, if any. No systems broke during testing.

Figure 13. Mid-back skin irritation caused by wearing the Vital Sign Detection System (VSDS) after four hours of training



Table 9. Sources of negative comments regarding various parts of the VSDS

	Extreme	Very	Moderate	Slight	No
	Negative	Negative	Negative	Negative	Negative
	Impact	Impact	Impact	Impact	Impact
Electrodes	0	0	0	2	10
Water Proof Material	0	0	0	2	10
Central Belt Area	0	0	0	4	8
Belt Elastic	0	0	0	3	9
Belt Elastic Stitching	0	0	0	4	8
Shoulder Belt Adjuster	0	0	2	1	9
Adjustment Fastener	0	0	0	4	8
Overall VSDS	0	0	0	4	8

When volunteers were asked if the VSDS was acceptable, 92% (11 of 12) said it was. The one individual who found the VSDS unacceptable said it was "because of the bulk of the chest piece." When asked "If the system would help medics or medical officers identify medical emergencies sooner, would you wear the system?", again all but one individual said they would. When volunteers were asked if they had any additional comments regarding the system, the following comments were provided:

• "I did not even notice I was wearing it; fit very well. I assume that I could wear it for 8 hours or more. I only wore it for about 1.5 hours."

- "I would like if you could make the chest piece smaller and thinner. Other than that I like the idea."
- "Smaller is better, lose the wires and build into a shirt."
- "The only hindrance was in the vest with wiring. The actual monitor was fine to wear. More sensors would be good, covering other areas of the chest and back for detection."

# **GRAPHICAL USER INTERFACE ASSESSMENT**

Of the 13 volunteers, 12 observed the computer screen that showed data being displayed in real-time as CST-WMD personnel completed their training exercise. Eight volunteers observed the screen approximately 1-5 mins, three volunteers observed the screen approximately 5-10 mins, and 1 volunteer (the physician assistant) observed the screen for approximately 8 hours over 2 days of testing. The screen that was available to be viewed was the Team List Screen (Figure 5 above). Ten volunteers thought this screen provided enough information, while two volunteers thought it did not provide enough information. One volunteer wanted individual names displayed, and the other volunteer felt the respiration rate values were not valid. Figure 14 shows utility ratings of the Team List Screen for CST-WMD personnel. Table 10 lists improvements to Team List Screen suggested by the test volunteers.

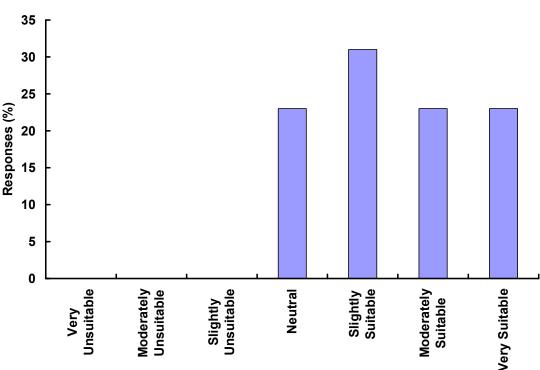


Figure 14. Utility ratings of the Team List screen for CST-WMD personnel

Table 10. Suggested improvements to the Team List Screen

Feature	N
List Individuals by Name	5
ECG Display	2
Blood Pressure	2
Temperature in both F and C	1
Color Code all Columns	1
Pulse Oximetry	1
Show Direction Person is Facing	1
Sort Individuals by Team Down Range	1
Show Accurate Time	1
Core Temperature	1
List Individuals Job Position	1
Do Not Have Automatic Screen Saver	1

Volunteers were also asked to provide feedback on GUI screens previously developed by U.S. Army medics (9) but not used in the present study (See appendix C). In addition to the twelve volunteers who wore the systems and the medical officer also completed this survey. Table 11 is a list of the various previously-developed concept screens and the "as is" ratings these screen concepts were given by the CST-WMD test volunteers. The highest rated screen was the Individual Warfighter Status screen with 77% of responses indicating moderately or very suitable ratings. All volunteers gave it better than a neutral rating. The lowest rated screen was the Squad Status screen with only 38% of volunteers giving it positive ratings and 31% of volunteers reporting it was slightly to very unsuitable for CST-WMD use.

Table 11. Ratings of the various concept screens that were previously developed from U.S. Army Medic feedback

	Concept GUI Screens Evaluated							
Ratings	Мар	Squad	Name	Individual	Treat	Medical	Reference	
	Location	Status	List	Warfighter	Administered	Field	Center	
				Status		Card		
Very Unsuitable	1	1	0	0	1	1	1	
Moderately Unsuitable	1	1	0	0	0	0	0	
Slightly Unsuitable	0	2	0	0	0	0	0	
Neutral	2	2	3	0	1	1	2	
Slightly Suitable	2	2	4	3	2	3	3	
Moderately Suitable	3	2	3	1	4	1	1	
Very Suitable	4	3	3	9	5	7	6	
% Favorable	54%	38%	46%	77%	69%	62%	54%	
Responses to Concept								

# **Map Screen Improvements**

The most frequently suggested improvements to the map screen would be to have buildings and streets represented on the map (n = 6) and a GPS reference on the

map (n = 3). Two individuals did not understand what the colored symbols on the map represented. The colored symbols represented the life-sign state of the Soldiers a medic is monitoring.

## **Squad Status Screen Improvements**

The most frequent suggestion to improve the squad status screen was to change "squad status" to "entry team" and "back-up team" status (n = 4). Others commented that a legend was needed (n = 1) and an ability to track the location of teams in the building was needed (n = 1).

## Name List Screen Improvements

Three improvements were suggested for the name list screen by one individual each: 1) the Ballistic Impact Detection System (BIDS) signal was not needed for CST-WMD personnel, 2) listing the type of PPE (personal protective equipment), and the amount of air remaining in the SCBA would be helpful, and 3) listing the distance from the cold zone (uncontaminated zone) would be useful.

# **Individual Warfighter Status Screen Improvements**

Two improvements were suggested for the individual Warfighter screen by one individual each. One individual suggested doing away with the BIDS figure and replacing it with information on core temperature, EGG, and body orientation. The second individual suggested adding information of the patient's duty position and section.

# **Treatment Screen Improvements**

Two individuals suggested that injuries and treatments be more aligned with problems and treatments associated with a CBRN environment. Other comments regarding this screen were also provided, including "keep this screen", "great", and "good information page."

#### **Medical Field Card Screen Improvements**

The only improvement suggested to this screen was to have the forms issued by first responders who work with the 1<sup>st</sup> CST-WMD, such as Massachusetts Emergency Medical Services. Other comments provided by one individual each regarding this screen was "awesome," "good for medical use," and "good to have an electronic copy on site in case the paper copy gets lost."

## **Reference Center Screen Improvements**

The only comment regarding improving this screen was that the language translator may not be necessary.

#### DISCUSSION

This study successfully demonstrated real-time physiological status monitoring of encapsulated 1<sup>st</sup> CST-WMD in an operationally-relevant field environment. The WPSM-IC VSDS, medical hub, COTS radio and COTS GPS systems were used. The

test and evaluation assessed the ability to acquire and transmit physiological information, acceptability of the system to CST-WMD personnel, usefulness of the physiological information to the medical officer, and suitability of GUI.

#### ABILITY TO PROVIDE REMOTE PHYSIOLOGICAL INFORMATION

The WPSM system, as configured with the VSDS sensor system and the COTS radio telemetry, performed in a reliable and apparently valid fashion. The validity of the physiological data generated by the VSDS was previously established in the laboratory (8) and as part of FDA 510k certification process. Real time physiological information was provided every 15 s for all team members fitted with a WPSM system over the course of the two training events with a minimal loss of data (mean data loss = 1.1%, ranging from 0% to 5%). Of the physiological data transmitted, almost all were within physiologically-reasonable bounds (98.7%). The quality of heart rate and skin temperature data was similar to the reference standard heart rate and skin temperature data collected during a VSDS laboratory validation study (8). However, the respiration rate data was greater and more variable than measured during similar activities in the laboratory validation study. Upon closer analysis, the VSDS firmware version (Semsoft4-0053.a90) was discovered to be an obsolete prototype version that had been used in error. Presumably, the poor performance of the respiration rate sensor can be attributed to this error. The same VSDS devices, with updated respiration rate detection firmware, have since been demonstrated to perform as expected (10).

Although the vital sign detection algorithm generated no false positives, the number of "blue" or "unknown" states reported was unacceptably high. Given that a less-stable and less-accurate version of the respiration rate algorithm was running in the VSDS, as discussed above, it is not surprising that their was a decreased confidence in the respiration rate data output by the algorithm. Furthermore, the nature of the vital sign detection algorithm is such that a single no-confidence event, e.g., out of bounds respiration rate, results in a three minute (15 data point) "blue state." Thus, a modest number of anomalous data points can result in a protracted "blue" state. For example, for one volunteer the VSDS did not exit the initial blue state for nearly two hours because the respiration rate confidence was not stable enough to allow a transition to a "green" state. Thus, the excessive number of "blue" state indications noted in this demonstration can reasonably be attributed to the errors in the respiration rate estimation associated with a firmware version error that has since been corrected.

#### **VSDS ACCEPTABILITY**

The VSDS was rated as acceptable by the majority of CST-WMD personnel in this study (92%). This is a substantial improvement over an evaluation of an earlier version of the VSDS where only 38% of respondents reported the system to be acceptable for military field use (5). There are two primary explanations for the differences in acceptability. First, results from the previous study resulted in design changes to the VSDS. These changes, which appear to have improved overall acceptability of the system, included the following:

- The center attachment area was reduced in size with the goal of reducing sweating and irritation in the chest area.
- The belt material in the front part of the VSDS was made softer and more breathable.
- The center piece of the belt where the SEM attaches was made more rigid to prevent the SEM from popping off of the belt. As a result, in the present study the SEM did not pop off at all, whereas in the previous study it occurred in 39% of the units (7).
- The large belt buckle in the back was replaced by small metal fasteners.

The second possible reason for improved acceptability was that in the current study volunteers only wore the device for an average of 4 hours with the longest wear time of 8 hours. In the previous study, volunteers were asked if the device was acceptable to wear for 8 hours or longer and wore the system for up to 120 hours of training over 7 days including one 24 hour sustained operation (5). Because of this difference and the small sample size, it is recommended that future testing with CST-WMD personnel include wearing the system for longer periods of time, include different types of training exercises, and include other CST-WMD units besides just the 1<sup>st</sup> CST-WMD to ensure the results can be generalized to the entire CST-WMD community.

One area that still needs improvement is to reduce the skin irritation associated with the shoulder belt adjuster and the adjustment fastener. Skin irritation in two individuals was reported after wearing the VSDS for less than 8 hours. Presumably, wearing the VSDS for longer periods of time would increase the severity of skin irritation or increase the frequency of those who may experience some skin irritation. Ideas for improvement offered by the test volunteers included building the system into a shirt, and making the chest piece smaller and thinner, although this last suggestion probably would not address the problem of skin irritation on the back.

When volunteers were asked if they would wear the system if it allowed medical personnel to better monitor their health state, 92% of volunteers said they would. This is comparable to the 89% of volunteers from a previous study who said they would wear that system as is if it would help medics save their life (5).

#### **USEFULNESS OF SYSTEM TO MEDICAL OFFICER**

The GUI used for this study would normally include multiple screens. However, only a Team List Screen was available for evaluation. The medical officer reported that he spent approximately 8 hours observing real-time physiological information. The medical officer suggested that having this information was a valuable supplement to the information he obtained from radio discussions with down-range personnel. The medical officer reinforced the usefulness of the system by suggesting that a PDA-based display of the real time data be used, so he could move around the incident site freely

but still be able to monitor the physiology status of his team without having to return to the base station display.

# SUITABILITY OF THE GRAPHICAL USER INTERFACE (GUI)

A GUI concept for the medical monitoring system was previously developed with experienced infantry medics (9). CST-WMD personnel offered, in general, positive comments on these previously developed GUI designs. As shown in Table 11, only two of the seven previously developed screens received less than 50% favorable responses. The squad status screen was not appropriate in this study because CST-WMD personnel do not operate in squads. However, it was suggested that squad status be changed to entry and back-up of reconnaissance or survey teams. In addition, it was suggested the BIDS (ballistic impact detection system) icon be removed from the main screen since this function is not relevant to the CST-WMD mission. It was recommended that having a note on the level of PPE on the Name-List screen would be helpful since CST-WMD wear different levels of PPE that impose varying levels of thermal strain. CST-WMD personnel broadly approved of the appearance and content of Name-List/Team List Screen. Under operational use, the names of individuals would be displayed, in contrast to this technology demonstration where individuals' names were not displayed to maintain medical data confidentiality.

Nine of the 12 volunteers thought the Individual Warfighter Status screen was very suitable for their use, but that the BIDS icon should be deleted. Other suggestions included adding information on personnel's core temperature, ECG, and body orientation, duty position, and section. Overall, only small changes appear to be needed for the GUI to meet the needs of the CST-WMD community. However, this was the first study with this potential customer and a small sample was used. A follow-up study with other CST-WMD units is warranted.

#### SYSTEM LIMITATIONS AND PLANNED IMPROVEMENTS

The physiological monitoring equipment used in this field training exercise had multiple subcomponents. That is, the VSDS, the hub, and a COTS radio with its battery pack. This bulk of equipment (4 boxes and connecting wires) could pose a problem for reliable continuous use in missions or during training, as noted in some of the user surveys. In addition, the COTS radio modems used to transmit the data back to a base station computer were adequate for this demonstration, but were operating near capacity and could not be readily scaled to use with larger groups. For example, when multiple repeaters were used to provide adequate radio coverage during the concrete tank portion of the training some repeater messages were lost. This indicates that adding more users could potentially stress the system to the point where radio messages could be lost entirely.

To address these limitations, a new VSDS is being developed which will be able to receive other sensor data directly, eliminating the need for a medical hub. In addition, this new VSDS will have the ability to (a) use core temperature (obtained from a thermometer pill) and heart rate data to calculate thermal/work strain or a

"Physiological Strain Index" (PSI) (11), and (b) through a newly developed algorithm predict core temperature of up to 20 minutes into the future with relative confidence levels (12). A number of commercial efforts are underway to improve data telemetry capabilities. Additional future work will concentrate on developing an integrated Thermal Injury Prevention System (TIPS), which will encompass mission planning tools such as the Heat Strain Decision Aid (HSDA) (13), real time monitoring with advanced sensors such heat flux sensors (14), and novel algorithms to predict thermal state.

#### CONCLUSIONS

The physiological information displayed in real time was found to be useful in the monitoring of CST-WMD personnel. The physiological monitoring system provided reasonable data with almost 100% continuous monitoring of all participating team members. However, the respiration rate measurements were found to be in error (i.e., they were too high) because of a firmware error. Nevertheless, the relative change in respiration rates was seen as useful by the CST-WMD medical officer.

The VSDS, although relatively large to be worn routinely on the chest, was generally found to be satisfactory for CST-WMD missions, and useful for monitoring of CST-WMD personnel in real mission situations of eight hours or less. It is likely that skin irritation will remain an issue for some individuals, especially if required to wear the VSDS for longer than 8 hours.

The GUI previously developed for combat medics, listed each individual CST-WMD team member and their medical status. This GUI was found to provide adequate information regarding individual health status. However, an additional "drill down" screen providing individual physiological status trends and current individual status was desired as an additional capability. Specific recommendations that make the GUI screens more applicable to CST-WMD needs, such as having entry teams displayed instead of squads, and adding level of PPE, should also be considered.

The current WPSM VSDS was demonstrated to provide CST-WMD with the medical monitoring telemetry basic capabilities detailed in the national CST-WMD working group requirements. Ongoing improvements to the WPSM system will provide the CST-WMD with a viable system to begin medical monitoring during select missions.

#### SPECIFIC RECOMMENDATIONS

- Test and evaluate the new VSDS version capable of receiving and interpreting core thermometer pill data.
- The VSDS adjustment buckle should be further refined to avoid rubbing and irritation.

- The overall size of the VSDS should be reduced to improve comfort and wear over an extended period of time.
- Confirm the functionality of the corrected respiration rate and vital signs detection algorithms.
- The WPSM display should be enhanced to include an individual's detail screen with time series data plots. The system should also be enhanced to allow the GUI to function on a PDA and receive health status message by wireless Ethernet (IEEE 802.11b/g). Future testing would include medical and/or command staff actually using the GUI on a preferred type of device (e.g., laptop computer, PDA, etc.).
- Software defined radio solutions should be identified that can reliably transfer digital
  data that can be readily accessed by third party applications. The radio should be
  capable of forming sophisticated short-range mesh networks and have the ability to
  link to repeaters for long range data transmission.
- Repeat testing with the enhanced equipment, a fully working GUI, with more volunteers, volunteers from different CST-WMD units, varying types of CST-WMD training exercises, and increasing the wear time of the system.

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#### **APPENDIX A**

National CST-WMD Medical Working Group Medical Monitoring Telemetry System Requirement Document. From Hoyt e-mail dated 2/21/07 this document title is 20070123.

## CSTWG Submission Title: <u>MEDICAL MONITORING TELEMETRY SYSTEM</u>

#### Capability Addressed (From TDA Para 6):

 $\underline{\textit{6J:}}$  Provide, for assigned personnel only, preventive medicine,  $\underline{\text{medical surveillance}}$  and  $\underline{\text{EMT-level medical care}}$ .

6C: Determine the current contaminated area and <u>assess current and potential hazards to personnel</u>, animals and selected critical infrastructure features resulting from identified agent/substance presence.

Submission Sub-Group (OPS, COMMO, MED, SURVEY, LOG): MEDICAL

Action Officer POC: MAJ DAVID DOMINGUEZ / 1LT DAVID DIGREGORIO / CPT EDWIN LEAVITT / LTC ROGER PRESZLER

Action Officer Unit: 95th CST / 1st CST / 32nd CST / 81st CST

Action Officer Email: david.dominguez1@us.army.mil / david.digregorio@us.army.mil / edwin.leavitt@us.army.mil / roger.preszler@nd.ngb.army.mil

Action Officer Telephone: 510-750-3157 / 508-294-2741 / 443-845-6295 / 701-426-0753

#### Suggested Technical Working Group Lead (PTWG, TTWG, ETWG): ETWG

- **1. PROBLEM:** Difficult to assess status of downrange personnel verbally. Most casualties demonstrate physiologic changes in vital signs and core temperature prior to collapse or loss of consciousness/death.
- 2. JUSTIFICATION: Proactive medical monitoring can decrease serious injuries and loss of operational strength/readiness by tracking changes and trends in vital signs/core temperatures and taking action before they become symptomatic and result in a medical emergency/"man-down" scenario.
- 3. SOLUTION CHARACTERISTICS: System characteristics need to have the following features/capabilities: AC/DC/Battery power; Ruggedized water resistant base station monitor and sensors capable of operating in harsh environments temperature of minus 20 up to 170 degrees. Base station requires audible and adjustable alarms. Able to tolerate humidity to 100%. Disposable oral capsule core temperature sensor; Disposable light weight heart rhythm sensor; Disposable light weight respiratory rate sensor; Disposable light weight oxymetry sensor; Ambient temperature sensor. Sensors need to be embedded into moisture wicking shirt. Wireless secure transmission of data in real-time, from sensors to monitoring station, with a distance capability of 2 miles over unobstructed open ground. Must be able to operate in confined space environment up to ½ mile; Must be able to monitor eight personnel simultaneously on a single receiving base station monitor; Must have data storage/trend graphing report capability. Must be portable as a set in a single pelican or other (rugged) type case. Must include service and technical support plan. Initial training upon fielding.

- **4. OPERATIONAL CONCEPT:** Operated and monitored by medical personnel and employed (worn) by entry, backup and decon team personnel during level-A or B suit operations total of eight simultaneously.
- **5. ORGANIZATIONAL CONCEPT:** Equipment addition. Operated by medical personnel. Sensors worn by all personnel in level-A or Level-B suits.
- **6. PROCUREMENT OBJECTIVE:** Each CST Team would require 2 base stations and any necessary signal repeaters. Also, would require multiple sets of disposable sensors per team.
- **7. SUPPORT REQUIREMENT:** Would require maintenance, calibration, service and training support from manufacturer annually (at a minimum).
- 8. AVAILABILITY: Several COTS systems are currently available that meet some or most of the requirements, but fall short of some key requirements. Specifically Life shirt does not offer Cardiac rhythm monitoring or Core temperature. MiniMitter has research accomplished for cardiac rhythm sensor however needs to be incorporated into Transmitter information.
- **9. RECOMMENDATION:** Medical Telemetry systems need to be evaluated and tested on several CST teams in various climates and under extreme conditions (hot and cold), before fielding a system to the CST 's.

#### **APPENDIX B**

## WPSM System Acceptability Questionnaire



The Vital Sign Detection System (VSDS) is a medical system that has been made to send life sign data to a medical station. The system measures breathing rate, heart rate, body position and activity. The VSDS will allow a medical officer to identify any medical problems sooner.

The VSDS that you have worn today is a new prototype. We would like to know your opinions about how you found wearing this device during your training exercise. By answering the questions below you will help us create a better product.

1. How long did you wear the VSDS?	hours
J J	

Fit

- 2. Did the Vital Sign Detection System fit you properly?
  - O Yes
  - $\bigcirc$  No  $\rightarrow$  If No: **2a.** Please explain why it did not fit you properly.

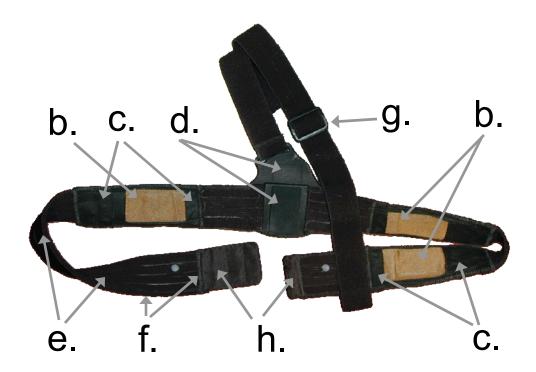
**3.** Using the following scale please rate how much you like or dislike the fit of the Vital Sign Detection System for the following areas:

	Dislike Very Much <b>1</b>	Dislike Moderately <b>2</b>	Dislike Slightly <b>3</b>	Neither L ke nor Dislike <b>4</b>	L ke Slightly <b>5</b>	L ke Moderately <b>6</b>	Like Very Much <b>7</b>
a. Overall	0	0	0	0	0	0	0
b. Chest	0	0	0	0	0	0	0
c. Shoulders	0	0	0	0	0	0	0
d. Neck	0	0	0	0	0	0	0
e. Back	0	0	0	0	0	0	0

**4.** Using the following scale please rate, how tight or loose, the fit of the Vital Sign Detection System was for the following areas:

	Very Tight	Moderately Tight	Slightly Tight	Neither Tight nor Loose	Slightly Loose	Moderately Loose	Very Loose
	1	2	3	4	5	6	7
a. Overall	0	0	0	0	0	0	0
b. Chest	0	0	0	0	0	0	0
c. Shoulders	0	0	0	0	0	0	0
d. Neck	0	0	0	0	0	0	0
e. Back	0	0	0	0	0	0	0

## **Comfort**



Please rate how comfortable or uncomfortable you found the VSDS during your training exercise. Rate the VSDS overall and for the individual parts of the belt listed for the question: (*Match the question letter to the belt area on the on the diagram above*).

5. COMFORT	Very Uncomfortable	Moderately Uncomfortable	Slightly Uncomfortable	Neither Comfortable nor Uncomfortable	Slightly Comfortable	Moderately Comfortable	Very Comfortable
	1	2	3	4	5	6	7
a. Overall	0	0	0	0	0	0	0
b. Cloth Electrodes	0	0	0	0	0	0	0
c. Water Proof Material	0	0	0	0	0	0	0
d. Central Belt Area	0	0	0	0	0	0	0
e. Belt Elastic	0	0	0	0	0	0	0
f. Belt Elastic Stitching	0	0	0	0	0	0	0
g. Shoulder belt adjuster	0	0	0	0	0	0	0
h. Adjustment Fastener	0	0	0	0	0	0	0

	e a particular activity more uncomfortable No	or activities during your training where you found the e?
0	Yes $\rightarrow$ If Yes:	<b>6a.</b> What was the activity?
		<b>6b.</b> Please rate the overall comfort of the VSDS during this activity: (Use the comfort scale above)
		<b>6c.</b> Please describe the activity and how the VSDS was uncomfortable.
		Activity 2:
		6d. What was the activity?
		<b>6e.</b> Please rate the overall comfort of the VSDS during this activity: (Use the comfort scale above)
		<b>6f.</b> Please describe the activity and how the VSDS was uncomfortable.

## **Performance**

Please rate whether the VSDS had an impact on your overall job performance and for the other activities listed:

7. Performance Impact	Not Applicable	Extreme Negative Impact <b>1</b>	Very Negative Impact <b>2</b>	Moderate Negative Impact <b>3</b>	Slight Negative Impact <b>4</b>	No Negative Impact
a. Overall impact on performance		0	0	0	0	0
b. Ease of motion		0	0	0	0	0
c. Ease of movement		0	0	0	0	0
d. Rolling	0	0	0	0	0	0
e. Jumping	0	0	0	0	0	0
f. Landing	0	0	0	0	0	0
g. Running	0	0	0	0	0	0
h. Assuming a firing position	0	0	0	0	0	0
i. Bending	0	0	0	0	0	0

## **Physical Impact**

## **Impact Scale**

Moderate Negative

Very Negative

Extreme

Negative Im	pact	Impact	Impact	Impact	Impact
1		2	3	4	5
8. During yo	ur training No	did the VS	DS cause any skin irrit	ation, or other disco	mfort?
0		If Yes:	8a. What was/were the	e problem/s?	

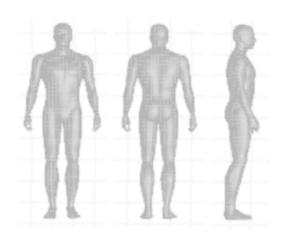
**8b.** Please rate the overall negative impact of the problem/s: \_\_\_\_\_ (*Use the impact scale above*)

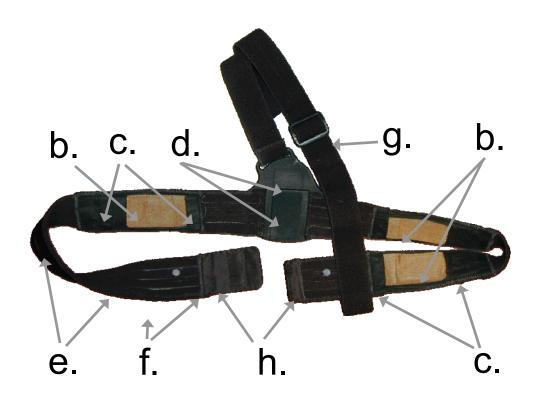
Slight Negative

No Negative

caused it.	e describe th	ie problem/s	and now	the VSD

**8d.** Please indicate on the diagram below where the problem occurred.





**9.** For each of the VSDS components listed below, please rate if there was any negative impact. (*Match the question letter to the belt area on the on the diagram above*).

	Extreme Negative Impact <b>1</b>	Very Negative Impact <b>2</b>	Moderate Negative Impact <b>3</b>	Slight Negative Impact <b>4</b>	No Negative Impact
a. Overall	0	0	0	0	0
b. Cloth Electrodes	0	0	0	0	0
c. Water Proof Material	0	0	0	0	0
d. Central Belt Area	0	0	0	0	0
e. Belt Elastic	0	0	0	0	0
f. Belt Elastic Stitching	0	0	0	0	0
g. Shoulder belt adjuster	0	0	0	0	0
h. Adjustment Fastener	0	0	0	0	0

## **Durability**

<b>10.</b> Did the Vital S	Sign Detection System co	me apart or break?
O Yes -		ase explain how the VSDS broke or came d how you fixed the problem.
	Acce	otability
O Yes	•	ended period of eight hours or more?
	<b>11a</b> . Please exp	plain why the system is not acceptable.
	were able to help medicsoner would you wear this s	/medical officers identify medical ystem during missions?
O Yes	3	
O No	→ If No:	
	<b>12a</b> . Please exp 	plain why you would not wear the system

Thank You

If you have any other comments please feel free to write them below or on the back of this survey.

#### **APPENDIX C**

ldentification	Number:	
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## **Civil Support Team – Weapons of Mass Destruction (CST-WMD)**

## **Medical System Computer Display**

#### Questionnaire

The medical telemetry system was designed to assess the medical status of downrange personnel, by presenting changes in vital signs and core temperature.

The medical computer display you saw today had two screens of information. The first screen (Team Screen) showed all CST-WMD personnel who were currently wearing a medical monitoring system. The second screen (Individual Screen) provided a more detailed view of an individual's medical information.

<b>1.</b> How lo	ng have you been in the CST-WMD?	years
2. What is	your primary role in the CST-WMD?	
-	ONLY observe the display, or did you use the mou mething on the display?	se and or keyboard to
0	Observed ONLY Changed the display with the mouse or keyboard	
4. How lor	ng did you observe or use the medical display?	
0 0 0 0	1 – 5 Minutes 5 – 10 Minutes 10 – 20 Minutes 20 – 30 Minutes 30 – 45 Minutes 45 – 60 Minutes More than 60 Minutes (please specify how long) Hours,	Minutes
5. Which s	screens did you see or use? (check all that apply)	
	Team Screen Individual Screen	

## **Team Screen**

			<b>Screen</b> providerous medical	e enough information to identify personnel who may be condition?
	0	Yes		
	0	No $\rightarrow$	If No:	<b>6a.</b> Please explain what information you would add.
			five things that rear of this qu	t could improve the <i>Team Screen</i> (feel free to add estionnaire).
a.				
b.				
C.				
d.				
e.				

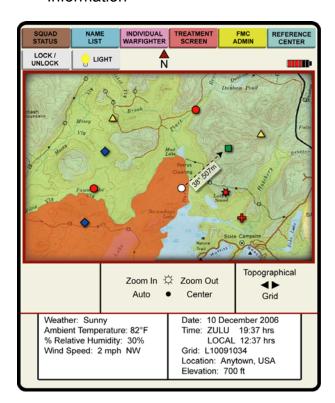
## **Individual Screen**

<b>8.</b> Does the <i>Individual Screen</i> provide enough additional medical information about a CST-WMD member?			
	0	Yes	
	0	$No \rightarrow If No:$	8a. Please explain what information you would add.
			t could improve the <i>Individual Screen</i> display (feel ar of this questionnaire).
a.			
b.			
C.			
d.			
e.			

## **Other Displays**

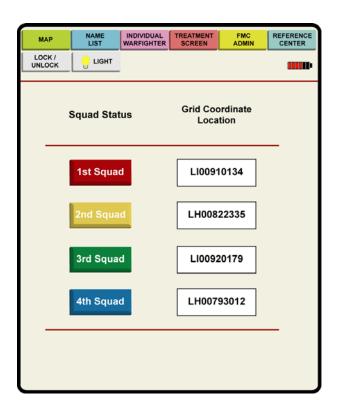
We have worked with a number of U.S. Army medics to help define what types of screens would be most useful for displaying and using medical monitoring information for their particular jobs. For each of the following screens please rate how suitable or unsuitable each screen would be for a CST-WMD medical monitoring system.

**10a.** Map Location and Environmental Information



- 0 Very Unsuitable (1) 0 Moderately Unsuitable (2)0 Slightly Unsuitable (3) 0 Neutral (4)0 Slightly Suitable (5)0 Moderately Suitable (6) $\circ$ Very Suitable
- **10b.** If applicable, describe how you you would change this screen for CST use.

11a. Squad Status



- 0 Very Unsuitable (1)  $\bigcirc$ Moderately Unsuitable (2) 0 Slightly Unsuitable (3)Neutral (4) Slightly Suitable (5)0 Moderately Suitable (6)Very Suitable (7)
- **11b.** If applicable, describe how would change this screen for CST use.

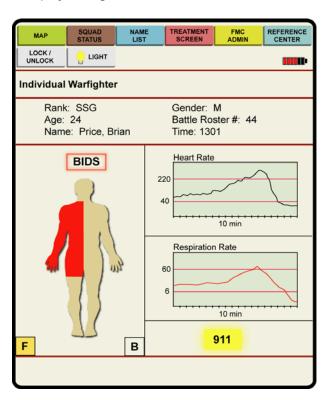
# **12a.** Name List, Location, and Physiology



0	Very Unsuitable	(1)
0	Moderately Unsuitable	(2)
0	Slightly Unsuitable	(3)
0	Neutral	(4)
0	Slightly Suitable	(5)
0	Moderately Suitable	(6)
$\bigcirc$	Very Suitable	(7)

<b>,</b>	(- /
<b>12b.</b> If applicable, descrived would change this scree	

# **13a.** Individual Warfighter's physiological status



0	Very Unsuitable	(1)
0	Moderately Unsuitable	(2)
0	Slightly Unsuitable	(3)
0	Neutral	(4)
0	Slightly Suitable	(5)
0	Moderately Suitable	(6)
0	Very Suitable	(7)

<b>13b.</b> If applicable, describe how you would change this screen for CST use.

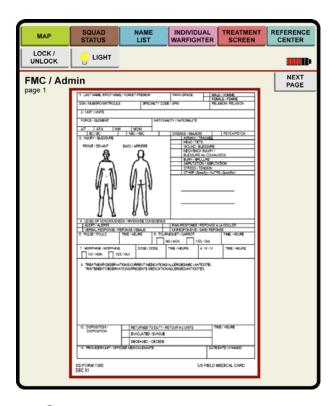
## **14a.** Treatment administered

#### INDIVIDUAL WARFIGHTER REFERENCE CENTER MAP LOCK / UNLOCK Treatment Screen **SSG Price Evacuation Status** Urgent **Immediate Priority** Routine Ground Air **Evacuation Type** Injury √ Sucking chest wound Treatment □ Pressure dressing √ Field dressing □ Abdominal wound √ Amputation √ Tourniquet □ Gunshot wound √ IV initiated Voice Recorder Blood Type: B-Medications: NONE Allergies: Nuts, Milk Products, Penicillin

0	Very Unsuitable	(1)
0	Moderately Unsuitable	(2)
0	Slightly Unsuitable	(3)
0	Neutral	(4)
0	Slightly Suitable	(5)
0	Moderately Suitable	(6)
0	Very Suitable	(7)

<b>14b.</b> If applicable, describe how you would change this screen for CST use.

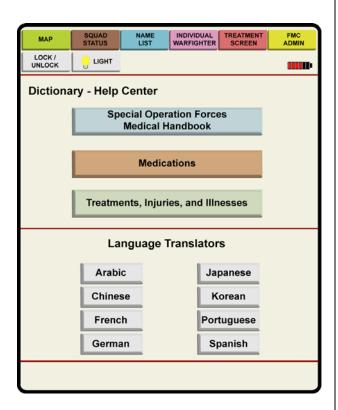
### 15a. Field Medical Card



O	Very Unsuitable	(1)
0	Moderately Unsuitable	(2)
0	Slightly Unsuitable	(3)
0	Neutral	(4)
0	Slightly Suitable	(5)
0	Moderately Suitable	(6)
0	Very Suitable	(7)

<b>15b.</b> If applicable, describe how you would change this screen for CST use.

### 16a. Reference Center



- 0 Very Unsuitable (1) 0 Moderately Unsuitable (2) 0 Slightly Unsuitable (3) 0 Neutral (4) 0 Slightly Suitable (5) 0 Moderately Suitable (6) Very Suitable (7)
- **16b.** If applicable, describe how you would change this screen for CST use.

<b>17.</b> Do you have any other comments that will help us design a better medical display for CST use?

~ Thank You ~

## **APPENDIX D**

Heart rate, respiration rate, skin temperature, equipment temperature, and vital sign state time series data for Day 1 and Day 2 for each volunteer.

Vital sign state is plotted on the main Y – axis (left) with the following values:

Green	"OK"	=	0
Yellow	"Look"	=	4
Red	"Look Now"	=	8
Gray	"Absence of Vital Signs"	=	12
Blue	"Unknown / Fault"	=	16

